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**Paired Editorial to: 12-year Trajectory of Health-Related Quality of Life in Gastric Bypass**

**Patients vs. Comparison Groups**

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**Running Head: PE to: 12-Year Changes in HRQOL**

The paired study “12-year Trajectory of Health-Related Quality of Life in Gastric Bypass Patients vs. Comparison Groups” is a welcome addition to the literature. It thoroughly reports prospectively obtained 12-year health-related quality of life (HRQOL) data after gastric bypass surgery, compared with two non-surgical groups (those that sought but did not undergo bariatric surgery, and those with severe obesity that did not seek surgery). It is an important contribution as little is known about HRQOL in the long term after treatment for severe obesity, and well designed and conducted HRQOL studies are needed to understand how patients feel and function after treatment <sup>1</sup>. Indeed, HRQOL was one of the “core” outcomes selected by patients and health professionals for a core outcome set for bariatric surgery <sup>2</sup>.

The study used two relevant and well-validated measures, including one obesity-specific measure (the IWQOL-LITE) and a generic measure (the SF-36). Together they will detect relevant issues, allow comparisons to be made with other studies and contribute to evidence syntheses if appropriate. The HRQOL study was also well designed and reported. Authors highlighted their rationale for measuring HRQOL data post-surgery, clearly stated that patients themselves completed the HRQOL measures, provided details of missing data, and were clear how information would be used to inform post-operative support for the individual.

The main drawbacks of the study acknowledged by the authors are that only 737/1156 (63.8%) of patients had 12-year HRQOL data (260/418 (62.2%) in the surgery group, 242/417 (58.0%) in non-surgery group 1, and 235/321 (73.2%) in non-surgery group 2), and the interventions were not randomized. These have important implications for the study’s

conclusions. HRQOL data is often missing for non-random reasons, for example patients may not return for follow-up or complete HRQOL measures if they have poor outcomes, such as weight re-gain <sup>3,4</sup>. The large proportion of data missing (i.e. > 20%) also means that results may not be generalizable and a higher response rate may have found different results. Response rates in this study could have been improved by the use of postal HRQOL questionnaires for those who did not return for follow-up.

Important baseline differences were noted between those who completed and did not complete 12-year HRQOL measures. Completers reported higher (better) baseline scores for some aspects of HRQOL and had a lower baseline BMI than non-completers. It is possible that patients with better HRQOL at baseline benefit more from surgery than those who have poor HRQOL. As the authors rightly say, this could have led to an overestimation of the benefit of gastric bypass on HRQOL in their study. It is not possible from this study to determine the factors that led to the observed improvement in scores.

The overestimation of results due to missing data could then be compounded by the lack of randomized groups in the study. Because the treatments were not allocated at random there is a risk of selection bias. Random allocation will equally distribute known and unknown baseline characteristics of participants between groups, so that any differences seen between groups can be attributed to the treatments and not some other confounding variable <sup>5</sup>.

Given the importance of HRQOL as an outcome of bariatric surgery, it is essential that it is measured alongside clinical outcomes and included within routine clinical assessment to improve the completeness of long-term data and our understanding of the whole impact of treatment. Additionally, it is recommended that every effort is made to encourage well-

designed and conducted randomised studies evaluating treatment in this clinical area. This is being achieved in the UK, where 12 bariatric centers are working together to conduct the By-Band-Sleeve study <sup>6,7</sup>. By-Band-Sleeve is comparing the three common surgical procedures, with HRQOL a co-primary outcome with weight loss. Thus far 1025 patients have been randomized successfully. The next challenge will be identifying the best ways of communicating HRQOL data alongside clinical data from randomized controlled trials to patients at the point of decision-making for surgery <sup>8</sup>.

**Disclosure statement**

The authors have no conflicts of interests to declare.

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